Is Buddy Taping as Effective as Plaster Immobilization for Adults With an Uncomplicated Neck of Fifth Metacarpal Fracture? A Randomized Controlled Trial

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IS BUDDY TAPING AS EFFECTIVE AS PLASTER IMMOBILISATION IN ADULTS WITH AN UNCOMPLICATED NECK OF FIFTH METACARPAL FRACTURE? A RANDOMISED CONTROLLED TRIAL.

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INTRODUCTION

Background

Fractures of the fifth metacarpal neck – boxer's fractures – are common, accounting for 20% of hand injuries(1) and 5% of fractures of the upper extremity.(2) They are usually the result of a closed fist strike and are associated with a young, working-age male demographic.(3, 4) As such, boxer's fractures can have a significant functional impact, and result in time off work, leading to wider social and economic effects.(5)

Uncomplicated boxer's fractures – minimally displaced, closed, isolated injuries, with a fracture angulation up to 70 degrees – are managed conservatively without surgery.(6, 7) A range of options exist, such as immobilisation in a cast, buddy taping of the ring and little fingers and functional strapping of the affected hand.(2, 8-13)

A 2005 Cochrane review found existing studies comparing interventions for boxer's fractures were underpowered to detect a difference in functional outcomes, and could not clearly recommend one modality over another.(2) In a more recent randomised controlled trial and meta-analysis, functional outcomes were similar.(9, 10, 14) Since discomfort, hand function and ability to work may be considered variably per clinician-patient interaction, the current

data is insufficient to provide consensus for the optimal management of patients with boxer's fractures.(2, 9)

Importance

Management options for boxer's fractures can affect a patient's ability to return to work, sports and hobbies.(15) Plaster casts immobilise the affected joint, which might lead to better anatomical healing and thus outcome.(6) However, a cast can necessitate time off work, or at least a modification to duties.(12) Comparatively, functional strapping or taping allows early mobilisation and as such might allow for earlier return to work and improved hand function.(10-12)

Existing literature has either been underpowered or unable to detect a difference in patient functional outcomes, or has concentrated on radiological and physical measurements.(2) Functional outcomes are patient-centred and arguably more important than surrogate outcomes. Health economic implications of management options have not been explored in studies thus far.(15)

The demographic associated with boxer's fractures is not always compliant with follow-up as evidenced in previous studies.(10, 16) A less cumbersome intervention, such as functional taping, might benefit the patient and reduce the need for orthopaedic follow-up, requiring fewer radiographic and specialist reviews.(16, 17) Outcomes at a patient, hospital and community level might be significantly influenced by management choice.

To date, no RCT or broader review has identified a superior treatment considering *both* hand function as well as resource use.(15) We hypothesise that buddy taping provides better functional outcomes to plaster casting, and may allow an earlier return to work.

Goal of This Investigation

The objective of this study was to assess if functional (buddy) taping of the ring and little fingers showed superior functional outcomes at twelve weeks compared to plaster immobilisation in the management of adult patients with boxer's fractures. Primary outcome was hand function as measured by the quickDASH questionnaire twelve weeks post injury. Pre-specified secondary outcomes included patient reported pain and satisfaction scores, time missed from work and sports, and health economic outcomes.

MATERIALS AND METHODS

Study Design and Setting

This was a randomised controlled trial conducted between March 2016 and December 2017 in the Emergency Departments of two public hospitals within the same health district in Southeast Queensland, Australia. The main campus is a 750-bed major metropolitan teaching hospital and the second campus, located twelve kilometres away, is an urban district hospital with 200 beds. The combined Emergency Department census in 2016 was 160,000 patients.

The study was designed and endorsed by emergency and orthopaedic specialists working at both hospitals. The study was approved by the Health District's Human Research and Ethics Committee and registered prior to commencement with the Australia and New Zealand

Clinical Trials Register (ACTRN12616000441415). We adhered to the CONSORT statement (http://www.consort-statement.org).

Selection of Participants

Patients were considered for the study if they had a suspected fifth metacarpal neck (boxer's) fracture. To be eligible for inclusion, a fracture needed to be confirmed on plain radiographs taken in two planes of view as per hospital protocol and guidelines. Patients were screened 24 hours a day, seven days a week.

Exclusion criteria were: age under 18 or over 70; open fracture; gross rotational deformity of the affected finger as judged by the treating clinical team; comminuted fracture; intra-articular fracture; associated tendon injury, poly-trauma or other significant injury at presentation; fracture angulation greater than 70 degrees; injury over one-week old at the time of presentation. The degree of accepted angulation was based on existing literature (6), and after consultation with and endorsement by the institution's orthopaedic team.

Eligible patients were provided with an information leaflet regarding the study. Written informed consent was obtained from the patient prior to enrolment. Patients were enrolled by the treating doctor, nurse practitioner or extended scope physiotherapist.

Treatment Allocation

We randomised patients using computer-generated block-randomisations, with blocks of ten for both hospitals. Sealed study packs were created using sequentially numbered opaque envelopes. Within each pack a smaller, sealed opaque envelope contained the study ID and randomisation arm.

Study packs were located in a designated display rack in the "minor injuries" areas of the Emergency Departments at both sites. Completed packs were placed in a sealed box next to the study packs. Once a suitable patient had been consented, the next sequentially numbered envelope was opened to reveal the allocated treatment arm.

Intervention

Patients were randomised to receive either buddy taping of the ring and little fingers or plaster cast immobilisation. The intervention arm involved buddy taping of the ring and little fingers of the affected hand allowing movement of the wrist and hand (Figure 1). The ring and little fingers were taped together at the proximal and middle phalanges. The control arm, the hospital standard practice, was cast immobilisation in an ulnar gutter cast applied in a position of safe immobilisation (Figure 2).

Buddy tape and plaster were applied by a designated plaster technician or the treating clinician when no plaster technician was available. All clinicians had received training in both buddy tape and plaster application. This is routine practice at both study sites.
In both groups, patients were instructed to have the allocated treatment (either buddy taping or plaster) applied for three weeks, and that the allocated treatment would be reviewed in fracture clinic at designated follow up times.

Patients in both groups were advised they could return to work when able with no pre-specified time off. Patients were given buddy tape and plaster care instructions – including advice to return to the ED if they had concerns about the applied treatment.

Figure 1. Buddy taping.

Figure 2. Position of safe immobilisation.

In both study arms, treating clinicians were instructed that fracture angle reduction was not required prior to the application of the allocated treatment. Blinding of treating clinician and patient was, by virtue of the interventions involved, not possible. The statistician was blinded to group allocation. Patients were followed up by the research team and a dedicated research nurse. Patients were followed up in clinic and if they did not present for follow up, they were contacted by phone.

Outcome Measures

The primary outcome was hand function at twelve weeks, measured using the validated Shortened Disabilities of the Arm, Shoulder and Hand (quickDASH)(18). This questionnaire reflects the patient's ability to do everyday tasks, and measures pain and disability as a result of their injury. The quickDASH questionnaire scores a patient's overall disability on a scale of 0-100, calculated from 11 questions. Higher scores equate to a higher degree of disability. The measure has been used previously when assessing functional outcomes of boxer's fractures(10) and has been validated for use in person as well as over the phone.(19, 20) QuickDASH scores were measured at twelve weeks as the primary outcome and compared between the two groups. Where possible, quickDASH scores were measured at three and six weeks to allow imputation at final analysis in case of possible loss-to-follow up at twelve weeks. The optional work and sports/performing arts modules of the quickDASH questionnaire were not included.

Secondary outcome measures included pain and satisfaction using a numerical rating score from zero to ten, where zero equated to no pain and ten to severe pain; and where zero equated to very unsatisfied, and ten to fully satisfied; return to work (days off), return to sports (days off), and a validated measure of overall health-related quality of life, the EQ-5D-3L questionnaire.(21) The EQ-5D-3L questionnaire asks patients to estimate their health on a scale of one to three (one being good health, three being poor health) in terms of mobility, self-care, usual activities, pain/discomfort and anxiety/depression, generating a score between five and 15, with a lower score indicating better overall health. EQ-5D-3L scores were calculated at presentation and at twelve weeks.(22) Pain and satisfaction were measured at week one and twelve.

Medicare is the publicly funded universal healthcare system in Australia, and as such there were no direct monetary costs for the patients enrolled in this study. Healthcare resource utilisation data were collected for the two study groups. These resources included equipment cost (buddy taping and plaster) and staff time. The cost of materials used for a plaster cast is estimated at $22 AUD, compared with $2 AUD for the cost of buddy taping. The cost of a plaster technician is estimated at $33/hr AUD.

Primary Data Analysis

The sample size calculated for the study was 98 patients – 49 in each arm. The sample size was based on the ability to detect a clinically significant difference in the quickDASH score (from 0-100) of ten points with a standard deviation of 20 points at twelve weeks, with a power of 80% and a two-sided α of 0.05. A minimally clinical important difference of ten points was based on existing recent literature.(10)

Analysis was by intention to treat (ITT). Patients with available outcome data were analysed according to group assignment. Additional sensitivity analyses including imputations and per protocol analysis were conducted. Imputation analysis involved using data from the last available follow up if primary outcome data at week twelve were not available. Per protocol analysis involved analysing the patients by their final allocation, rather than the group they were randomised into.

Data were entered into a Microsoft Excel spreadsheet and then analysed in R, version 3.4.2. Prior to analysis, variables were reviewed for accuracy of data entry, missing values and outliers. QuickDASH scores were not normally distributed (Shapiro-Wilk Normality Test, $p < 0.01$), the Mann-Whitney test was performed to compare the quickDASH score between the two groups. For secondary outcomes we report medians, interquartile range (IQR) and 95% confidence intervals as appropriate.

Pre-specified secondary health economic outcomes were reported from the perspective of Queensland Health, Australia. . All costs are reported in 2016 Australian dollars (AU$1 ~ US$0.75).

RESULTS

Characteristics of Study Subjects

506 patients with presenting complaints suggestive of boxer's fractures were considered for inclusion with Figure 3 outlining reasons for non-inclusion. 126 patients were randomised and 97 patients with primary endpoint were available for ITT analysis (Figure 3). Baseline demographics of the study population are described in Table 1. Patients were predominantly young (26.5 years old) and male (85%) and right hand dominant (90%). The most common

employment type in both buddy tape and plaster groups was technical/trade (35% vs 39%), and in both groups approximately one-third played a sport as their main hobby.

Main Results

At twelve weeks, patients in both groups reported a median quickDASH score of 0, indicating absence of disability, with no significant difference between the two groups, p 0.557 (Figure 4). Patients randomised to the buddy group returned to work earlier than those randomised to the plaster group. Patients with buddy taping missed no days of work (IQR 0-7), compared to patients immobilised in a plaster cast who missed a median average of 2 (IQR 0-14) days of work. There was no difference in days missed from hobbies, activities and sports between the two groups (buddy: median 30 days, IQR 23-35 days; plaster: median 35 days, IQR 0-41 days), summarised in Table 2. There was no difference in EQ-5D-3L score between the two groups at twelve weeks (Table 2). Patients had similar pain and satisfaction scores at one and twelve weeks (Table 2), with patients in both groups reporting absence of pain and high satisfaction with treatment.

Three patients (all randomised to the buddy group) underwent operative management. In the first two cases, at fracture clinic, the treating orthopaedic consultant felt the injuries were intra-articular and a shared decision with patients led to operative management. In the third case, the patient had reinjured the affected limb at six weeks, was placed in plaster and underwent operative management. Five patients in the buddy group were changed to plaster cast, four at first fracture clinic follow up, and one patient when representing to the Emergency Department two days after randomisation requesting a cast. Seven patients in the plaster group were switched to buddy strapping at the first follow-up appointment (Figure 3). In both groups, crossover was a combination of patient and treating clinician preference.

Where possible repeat quickDASH scores were taken at three and six weeks; overall score was higher than at twelve weeks for both groups, with a sequential reduction in median score over time (Figure 4). Sensitivity analyses were undertaken with analysis by imputation, as well as per-protocol, analysed by the final treatment arm they received which includes patients who crossed over . In imputation analysis, patients lost to follow up at twelve weeks were included using their lasts available data, either at week one, three or six, carried forward. A total of 109 patients were analysed in the imputation analysis, with 54 in the buddy group and 55 in the plaster group respectively. Both analyses did not affect overall results.

Median length of stay in the Emergency Department was shorter by over half an hour for those randomised to the buddy group compared to the plaster group (buddy group 140 min - IQR 98-201, 95% CI 116-160; plaster group 176 min - IQR 123-236, 95% CI 141-193; difference 36 minutes).

Of the patients who attended follow up appointments and received repeat plain radiographs, no complications – such as infection, non-union, delayed union – were reported. Fracture angle at follow up was similar for both groups (median 32.6 degrees for buddy group (IQR 20-44), 28.1 degrees for plaster group (IQR 10-38.65)).

LIMITATIONS

There are several limitations to this study. This study was designed as a superiority study, however based on the assumption that buddy taping would give the same results with less resource use, a non-inferiority design would have been preferable. A post-hoc sample size

calculation for a non-inferiority design showed that based on a non-inferiority margin of 10 points on the quickDASH (same as used in prior research(10)) and a standard deviation of 10 points and a 90% power, a sample size of 21 per group would have been required, suggesting that despite the superiority design, our sample would have supported a non-inferiority conclusion.

Forty-one potentially eligible patients were not considered for inclusion by the treating clinician, and 34 patients declined to participate (Figure 3). Patients were missed due to other clinical priorities in a busy work place environment. These potentially eligible patients had similar demographics as the patients that were included, making selection bias unlikely.

The quickDASH score asks patients to report hand function related to the seven days prior. We measured the baseline (pre-injury) quickDASH score to identify patients with pre-existing decreased function. High pre-injury quickDASH scores were reported at baseline in both groups. However, since most patients had good functional outcomes at 12 weeks, this suggests that some patients may have erroneously reported their post-injury function – accounting for high baseline scores. There was no statistically significant difference in baseline quickDASH between the groups, indicating this occurred in a similar manner in both groups. Equally, other baseline demographics were evenly distributed, and as such a baseline imbalance in function is unlikely, leaving the primary outcome still valid. We suggest that future research asks specifically about both pre and post-injury quickDASH scores at baseline.

We were unable to obtain objective measurements of grip strength and range of motion, something that was intended in the study protocol. This was due to logistical barriers during

fracture clinic follow up. Where patients did attend follow-up clinic, repeat radiographs and fracture angle measurements were taken as planned. Since our functional outcome was similar between groups, we believe that grip strength and range of motion were unlikely to vary greatly between groups.

When patients failed to attend follow-up in person, quickDASH assessments occurred by phone. This was anticipated in the study protocol and verbal quickDASH assessments have been previously reported to be reliable and valid.(19, 20) Although we cannot exclude the potential for inaccuracies in phone assessments, such an effect would have been similar for both groups.

Seven patients in the plaster group and five patients in the buddy group crossed over to the alternative treatment arm. In each case this was a combination of patient request and clinician discretion. Our primary analysis was intention to treat, although we tested robustness of our findings using imputation and per protocol analysis which found similar results.

Three patients in the buddy taping group underwent operative management. In one patient this was due to a repeat injury. The other two patients underwent operative management at the discretion of the orthopaedic clinician, who felt the injuries to be intra-articular. We are unable to comment on whether these decisions were related to treatment allocation.

Several secondary outcomes, including variables of a health economic nature, such as days off work, time spent in ED and unit cost of treatment were measured; however a formal cost

analysis was not conducted. The study was not powered to show differences in secondary outcomes.

Lastly, study participants, treating clinicians and researchers were unable to be blinded to allocation by virtue of the nature of the intervention. Although some secondary outcomes may have been affected by this, we believe it is unlikely primary outcome assessment would be affected, since at twelve weeks neither group had any form of immobilisation in place.

DISCUSSION

Patients in both the buddy taping and plaster groups had the same good functional outcomes, as measured with the quickDASH questionnaire. Patients randomised to the buddy taping group returned to work earlier than those randomised to the plaster group. Pain and satisfaction scores were similar for both groups at one and twelve weeks. There was no difference in overall quality of life using EQ-5D-3L scores between the two groups at twelve weeks. Of those patients who attended follow up clinic appointments and received follow up radiographs, there were no complications in either group, and healed fracture angles were similar. Patients randomised to the buddy taping group spent, on average, 36 minutes less time in the emergency department than those randomised to the plaster group.

The results show that in patients with boxer's fractures, buddy taping resulted in similar outcomes compared to plaster casting with regards hand function and other pre-specified secondary outcome measures at twelve weeks. Patients randomised to the buddy taping group missed less time from work and were able to return to predominantly trade and labour roles that a plaster cast might negate from performing.

These outcomes have implications for patient follow up. With no discernible impact on fracture healing and function, patients in buddy taping could be followed up in community settings such as family practice clinics, rather than in hospital orthopaedic clinics, as is current practice in our hospital for patients with plaster casts.

Patients randomised to buddy taping spent less time in the emergency department than those in the plaster group. We postulate that this is because buddy taping is quick and easy to apply and does not require the expertise of a plaster technician. This has benefits for both emergency and orthopaedic departments. Clinicians in the Emergency Department can treat patients quickly and effectively, while plaster technicians can remain dedicated to other injures either in the Emergency Department and orthopaedic fracture clinics.

Patients in our study returned to work earlier than those in previous studies. In the buddy group, we postulate the earlier return to work (median time missed 0 days, compared to 22 days in one previous study(10)) may have been due to a positive drive among clinicians to encourage patients to return to work when able. In the plaster group, we had expected patients to have taken more than two days off due to the restriction of a cast. Indeed, in one previous study, patients missed on average a month of work.(10) It is conceivable that patients in the plaster returned to work on lighter duties, and future research could establish if this is the case. Alternatively, phone follow up may have introduced recall bias.

A plaster cast is usually applied by a trained plaster technician at $33/hr and the cost of materials required for buddy taping is cheaper than plaster casting (buddy taping less than $2 AUD, plaster cast $20 AUD). Buddy taping can be applied directly by the treating clinician

with no extra specialist service. Hence buddy taping represents a unit material cost saving, and reduces emergency department resources.

Our study demographic is comparable with patient demographics in previous studies, and thus we believe our results are generalisable to other high-income countries. The suboptimal rate of clinic follow up seen in previous studies was also reflected in our own.(10, 16) However, the study design allowed for follow up to be conducted by phone, resulting in higher follow-up rates at similar time-frames as reported in previous literature.(10) Since hand function at twelve weeks were reported as optimal by patients in both groups, this likely would be sustained for the longer term as well.

Based on the patient centred outcomes of our trial, and in context of other published evidence, we recommend a minimal intervention such as buddy taping for the management of uncomplicated boxer's fractures.(15) Such an intervention has similar functional outcomes for the patient compared to plaster immobilisation, seems to allow an earlier return to work, and saves resources in both the emergency and orthopaedic departments.

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TABLES AND FIGURES

Figure 1. Buddy strapping.

Figure 2. Cast immobilisation in position of safe immobilisation.

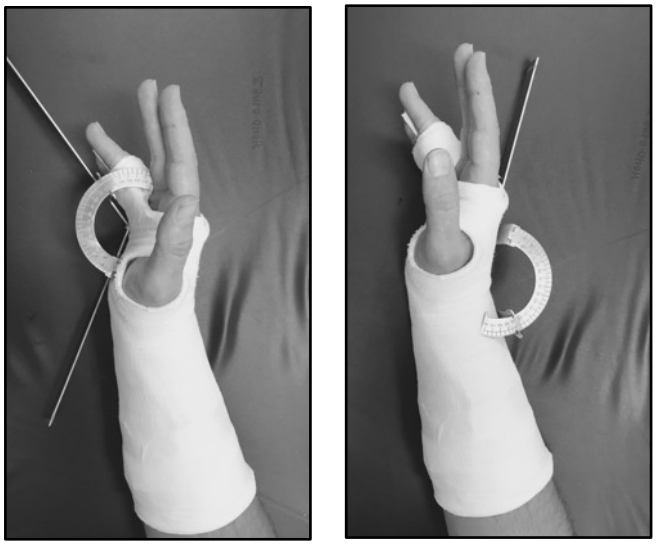
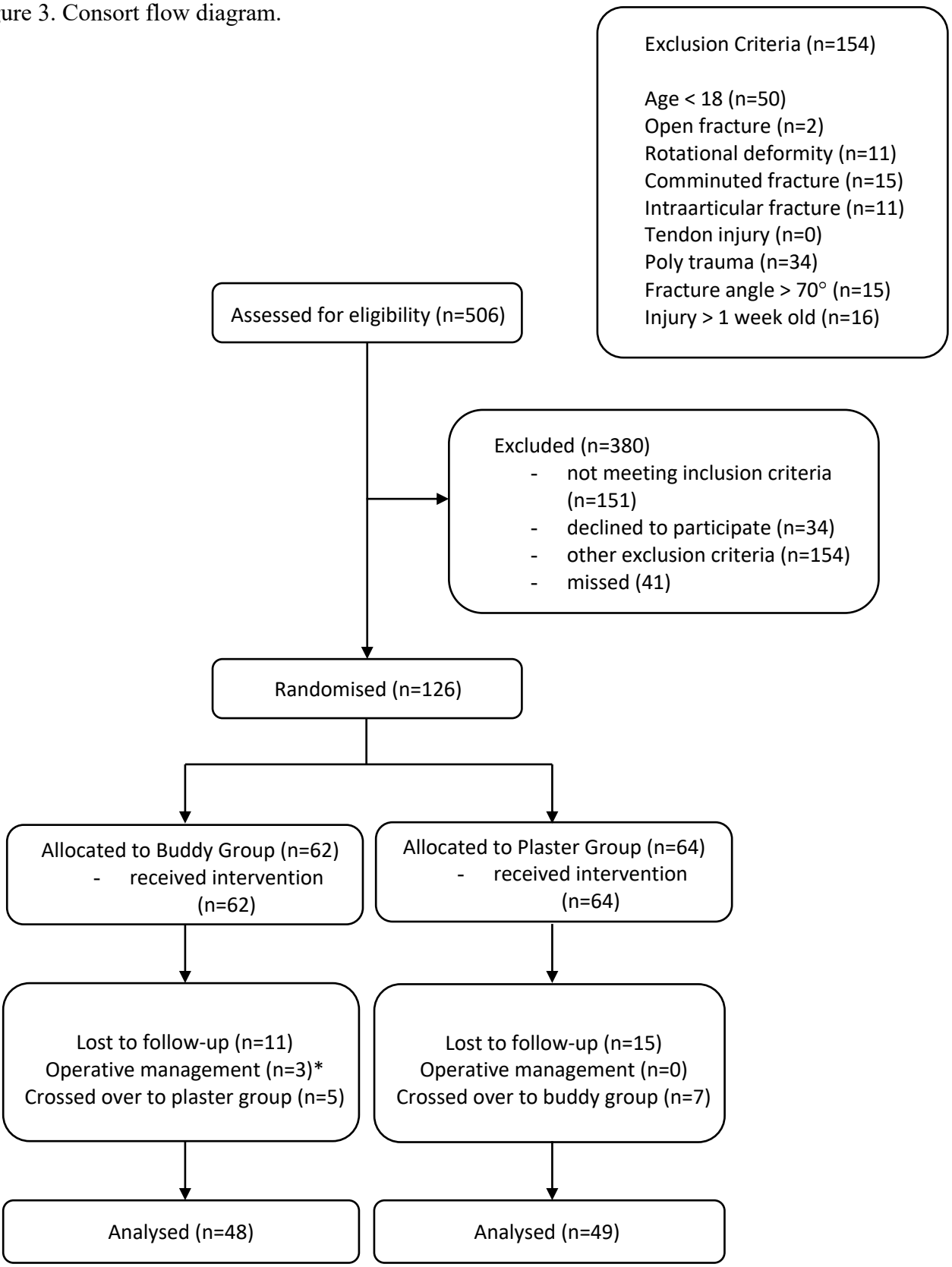


Figure 3. Consort flow diagram.



*patients undergoing operative management excluded from final analysis

Table 1. Baseline demographics.

	Buddy (n=62)	**Plaster (n=64)**
Week 0		
Age, median (IQR)	26 (20, 38)	27 (20, 34)
Male Sex, n (%)	51 (82.2)	56 (87.5)
Left Handed, n (%)	6 (9.7)	6 (9.4)
Occupation, n (%)		
Manager	4 (6)	6 (9)
Professional	10 (16)	5 (8)
Technical and Trade	22 (35)	25 (39)
Community and Personal Services	9 (15)	14 (22)
Clerical and Administrative	1 (2)	2 (3)
Sales	4 (6)	2 (3)
Machinery Operators and Drivers	3 (5)	1 (2)
Unemployed	9 (15)	9 (14)
Hobbies, Activities, Sports Class, n (%)		
Sport	25 (40)	24 (37.5)
Social	0 (0)	1 (2)
Arts	0 (0)	0 (0)
Outdoors	8 (13)	15 (23)
None	29 (47)	24 (37.5)
EQ-5D-3L Score, median (IQR)	5 (5,6)	5 (5, 6)
Premorbid quickDASH Score, median (IQR)	0 (0, 11.36)	6.8 (0, 22.7)
Fracture angle at presentation, degrees (median, IQR)	28.7 (10, 40)	30.8 (16, 43)

*outdoors included activities such as walking, hiking, gardening, fishing

Table 2. Secondary Outcome Measures.

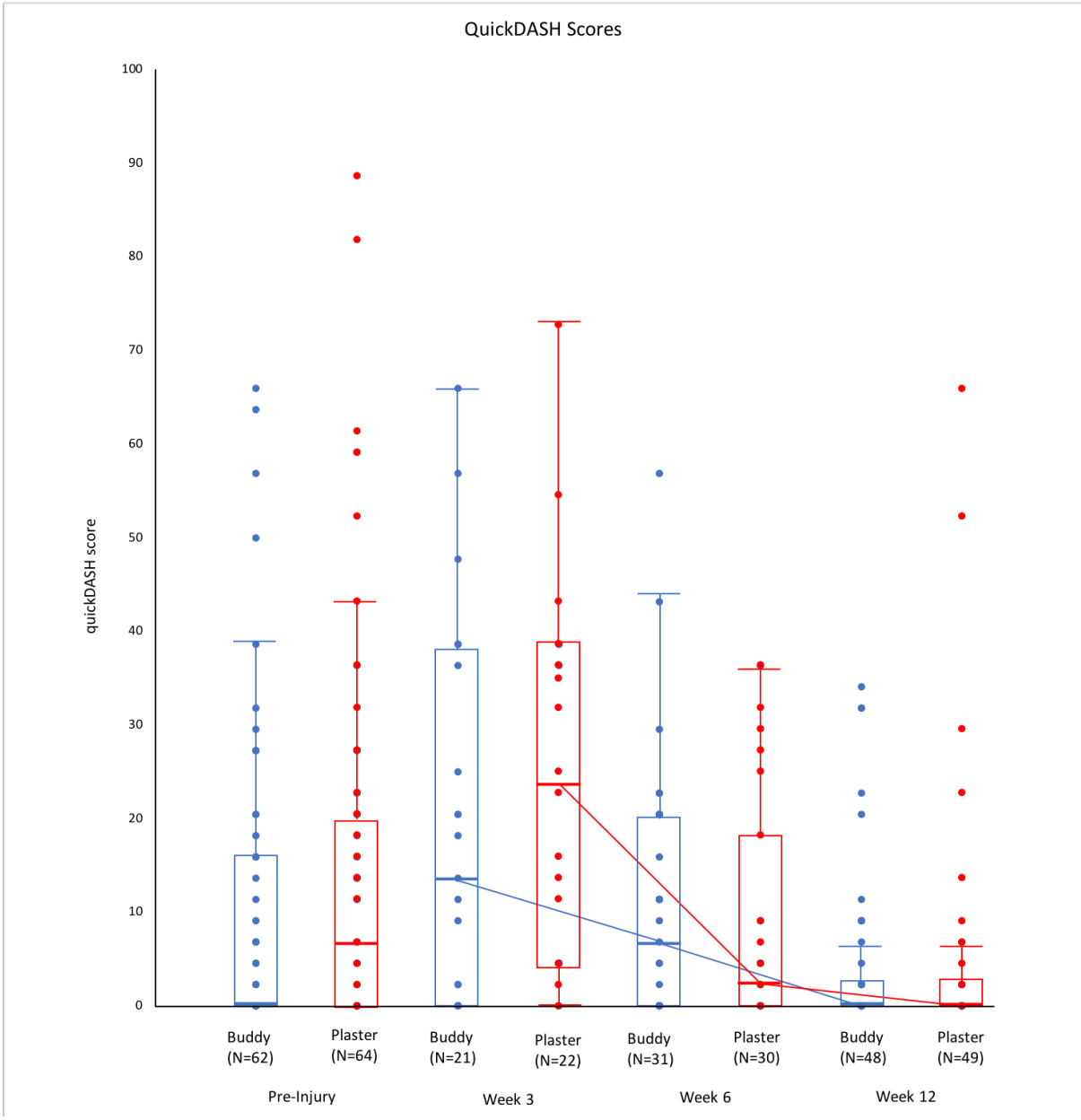
	Buddy Group (n=48)	**Plaster Group (n=49)**	**Difference between groups (delta: Buddy – plaster)**	**95% CI of delta**
Secondary Outcome Measures				
EQ-5D-3L score week 12, median (IQR)	5 (5, 6)	5 (5, 6)	0	[0, 0]
Pain Score at week 1, median (IQR)	0 (0,3)	0 (0,3)	0	[0, 0]
Pain Score at week 12, median (IQR)	0 (0, 0)	0 (0, 1)	0	[0, 0]
Satisfaction score at week 1, median (IQR)	9 (7, 10)	9 (8,10)	0	[-1, 1]
Satisfaction score at week12, median (IQR)	9 (8, 10)	9 (8, 10)	0	[0, 1]
Days missed work, median (IQR)	0 (0, 7)	2 (0, 14)	1	[0, 3]
Days missed hobbies, sports , median (IQR)	30 (23, 35)	35 (0, 41)	0	[-8, 12]
Median repeat fracture Angle, degrees , median (IQR)	32.6 (20, 44)	28.1(10, 38.65)	5	[-2.4, 14.9]

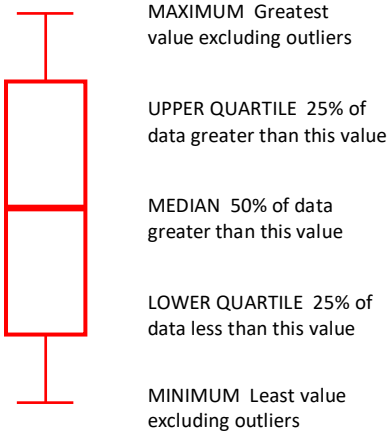
*EQ-5D-3L, 5-15, higher score indicating worse health

*pain on visual analogue scale, 0-10, 10 higher score indicating worse pain

*satisfaction on visual analogue scale 0-10, 10 higher score indicating greater satisfaction

Figure 4. QuickDASH scores over time.





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